

PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Form 1449/PTO


**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)

Complete if Known

| | |
|------------------------|-----------------|
| Application Number | 10/608,579 |
| Filing Date | 06-27-2003 |
| First Named Inventor | Browning et al. |
| Art Unit | 3739 |
| Examiner Name | Cohen, Lee S. |
| Attorney Docket Number | 13274 |

Sheet 1 of 4

| U. S. PATENT DOCUMENTS | | | | | |
|------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| [Signature] | A1 | US- 4,229,479 | 10-21-1980 | Brick et al. | |
| | A2 | US- 4,379,454 | 04-12-1983 | Campbell et al. | |
| | A3 | US- 4,457,748 | 07-03-1984 | Lattin et al. | |
| | A4 | US- 4,458,686 | 07-10-1984 | Clark, Jr. | |
| | A5 | US- 4,705,682 | 11-10-1987 | Moeller et al. | |
| | A6 | US- 4,777,954 | 10-18-1988 | Keusch et al. | |
| | A7 | US- 4,821,733 | 04-18-1989 | Peck | |
| | A8 | US- 4,975,441 | 12-01-1990 | Gibson | |
| | A9 | US- 5,023,085 | 06-11-1991 | Francoeur et al. | |
| | A10 | US- 5,036,861 | 08-06-1991 | Sembrowich et al. | |
| | A11 | US- 5,076,273 | 12-31-1991 | Schoendorfer et al. | |
| | A12 | US- 5,135,480 | 08-04-1992 | Bannon et al. | |
| | A13 | US- 5,139,023 | 08-18-1992 | Stanley et al. | |
| | A14 | US- 5,140,985 | 08-25-1992 | Schroeder et al. | |
| | A15 | US- 5,143,071 | 09-01-1992 | Keusch et al. | |
| | A16 | US- 5,203,327 | 04-20-1993 | Schoendorfer et al. | |
| | A17 | US- 5,279,543 | 01-18-1994 | Glikfeld et al. | |
| | A18 | US- 5,291,887 | 03-08-1994 | Stanley et al. | |
| | A19 | US- 5,302,172 | 04-12-1994 | Sage et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
|  | A20 | EP 0 295 092 A2 | 12-14-1988 | Scott et al. | | |
| | A21 | EP 0 613 942 A1 | 09-07-1994 | Su | | |
| | A22 | EP 0 804 155 B1 | 11-05-1997 | Gyory | | |
| | A23 | WO 96/00110 | 01-04-1996 | Tamada et al. | | |
| | A24 | WO 00/01351 | 01-13-2000 | Kirby et al. | | |
| | A25 | WO 00/33812 | 06-15-2000 | Miranda et al. | | |

Examiner Signature [Signature]

Date Considered 7/25/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

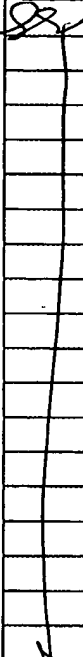
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

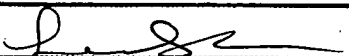
| | |
|------------------------|-----------------|
| Application Number | 10/608,579 |
| Filing Date | 06-27-2003 |
| First Named Inventor | Browning et al. |
| Art Unit | 3739 |
| Examiner Name | Cohen, Lee S. |
| Attorney Docket Number | 13274 |

Sheet 2 of 4**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--|-----------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
|  | B1 | US- 5,334,138 | 08-02-1994 | Sage et al. | |
| | B2 | US- 5,358,714 | 10-25-1994 | Green | |
| | B3 | US- 5,441,048 | 08-15-1995 | Schoendorfer | |
| | B4 | US- 5,443,080 | 08-22-1995 | D'Angelo et al. | |
| | B5 | US- 5,498,420 | 03-12-1996 | Edgar et al. | |
| | B6 | US- 5,603,693 | 02-18-1997 | Frenkel et al. | |
| | B7 | US- 5,636,632 | 06-10-1997 | Bommannan et al. | |
| | B8 | US- 5,668,170 | 09-16-1997 | Gyory | |
| | B9 | US- 5,686,516 | 11-11-1997 | Tzur | |
| | B10 | US- 5,693,604 | 12-02-1997 | Su | |
| | B11 | US- 5,760,096 | 06-02-1998 | Thornfeldt et al. | |
| | B12 | US- 5,800,685 | 09-01-1998 | Perrault | |
| | B13 | US- 5,874,095 | 02-23-1999 | Deckner et al. | |
| | B14 | US- 5,921,925 | 07-13-1999 | Cartmell et al. | |
| | B15 | US- 5,952,000 | 09-14-1999 | Venkateshawran et al. | |
| | B16 | US- 5,954,685 | 09-21-1999 | Tierney | |
| | B17 | US- 5,993,848 | 11-30-1999 | Suzuki et al. | |
| | B18 | US- 6,180,416 B1 | 01-30-2001 | Kumik et al. | |
| | B19 | US- 6,233,471 | 05-15-2001 | Berner et al. | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---|--------------------------------|--|--|----------------|
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | A20 | | | | | |
| | A21 | | | | | |
| | A22 | | | | | |
| | A23 | | | | | |
| | A24 | | | | | |
| | A25 | | | | | |

Examiner
SignatureDate
Considered

7/25/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

(Use as many sheets as necessary)

| | | | |
|-------|---|----|---|
| Sheet | 3 | of | 4 |
|-------|---|----|---|

Complete if Known

| | |
|------------------------|-----------------|
| Application Number | 10/608,579 |
| Filing Date | 06-27-2003 |
| First Named Inventor | Browning et al. |
| Art Unit | 3739 |
| Examiner Name | Cohen, Lee S. |
| Attorney Docket Number | 13274 |

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | A20 | | | | | |
| | A21 | | | | | |
| | A22 | | | | | |
| | A23 | | | | | |
| | A24 | | | | | |
| | A25 | | | | | |

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document, by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|---|------|--------------------------|-----------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/608,579 |
| | | Filing Date | 06-27-2003 |
| | | First Named Inventor | Browning et al. |
| | | Art Unit | 379 |
| | | Examiner Name | Cohen, Lee S. |
| Sheet 4 | of 4 | Attorney Docket Number | 13274 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| ger | D1 | BARRY, B.W.; Novel Mechanisms and Devices to Enable Successful Transdermal Drug Delivery; European Journal of Pharmaceutical Sciences 14 (2); 2001; pp 101-114; Elsevier | |
| ↑ | D2 | BERTI, JEFFREY J. et al.; Transcutaneous Drug Delivery: A Practical Review; Mayo Clinic Proceedings; June, 1995; Vol 70(6); pp 581-586 | |
| | D3 | HSU, CHANG-SHAN et al.; Anionic Gels as Vehicles for Electrically-Modulated Drug Delivery. I. Solvent & Drug Transport Phenomena; Pharmaceutical Research; Vol 13, No 12; 1996; PP. 1865-1870 | |
| | D4 | KANIKKANNAN, N. et al.; Structure-activity Relationship of Chemical Penetration Enhancers in Transdermal Drug Delivery; Current Medicinal Chemistry; 2000; 7; pp. 593-608 | |
| | D5 | PANCHAGNULA, RAMESH; Transdermal Iontophoresis Revisited; Next Generation Therapeutics; pp. 468-473 | |
| | D6 | PECK, KENDALL; Flux Enhancement Effects of Ionic Surfactants Upon Passive & Electroosmotic Transdermal Transport; J. of Pharmaceutical Sciences; Vol 87; 9; 09/98; pp. 1161-1169 | |
| | D7 | SANDERSON, JOHN E.; Iontophoretic Delivery of Nonpeptide Drugs: Formulation Optimization for Maximum Skin Permeability; J. of Pharmaceutical Sciences; Vol 78; No 5; 05/89; pp. 361-364 | |
| | D8 | VYAS, S.P.; et al.; Percutaneous Permeation: Principles, Means and Methods to Enhance the Permeation; Indian Drugs; 37(10; October, 2000; pp 454-463 | |
| | D9 | WANG, YOU MIN et al.; Effect of Sodium Dodecyl Sulfate on Iontophoresis of Hydrocortisone Across Hairless Mouse Skin; Pharmaceutical Development & Technology; 5(4); pp. 533-542; 2000 | |
| ↓ | D10 | XU, PING et al.; Enhanced Skin Permeability for Transdermal Drug Delivery: Physiopathological & Physicochemical Considerations; Critical Reviews in Therapeutic Drug Carrier Systems; 8(3) PP. 211-236; 1991 | |

| | | | |
|--------------------|--|-----------------|---------|
| Examiner Signature | | Date Considered | 7/25/05 |
|--------------------|--|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.